June/July 2018

InTouch

THE TOPRA NEWSLETTER – KEEPING MEMBERS IN TOUCH

In this issue...

It is time to enjoy the summer weather and, like every year, it is also time for the TOPRA Board elections. The nominations are now open. If you want to make a difference and lead our professional body, please see page 3 for more information about the roles.

As a result of the commitment to lifelong learning and progress, TOPRA has developed the Summer School. This is a great opportunity to advance your regulatory career this summer. Its programme includes two courses and the chance to receive two on-demand webinars for free .

Last but not least, the regulatory affairs specialist apprenticeship standard has been approved (see p2). This will encourage new talent into all areas of the regulatory affairs profession.

Raquel Lopez
Associate Scientific Assessor, UK Medicines and Healthcare products Regulatory Agency
Co-Editor, InTouch

Making good use of time

ANGELA STOKES, TOPRA PRESIDENT

What can we do to improve our work-life balance? Planning is essential but, more than that, ensuring we have strategies in place to ensure the effectiveness of that planning is paramount.

Summer is usually when we go on holidays and have family gatherings. At this part of the year, I find myself thinking about time itself. It is something that rules our days and, no matter what happens, we cannot slow it down, change it or redefine it. Many of us are so busy we find we are time-poor when it comes to families and friends, and I am notorious for trying – and failing – when it comes to juggling my days to allow all the necessities to blend seamlessly with the nicer things in life.

So are you good at planning when it comes to your career and professional development? If you would like to learn more about project management, TOPRA is running a **two-day course from 2–3 August** as part of the **TOPRA Summer School**. You can book this as a standalone course or, if you combine this with a course on **document writing and management** from 31 July to 1 August, you will receive two free on-demand webinars from a choice of nine. The topics include:

- Identification of medicinal product landscape
- Introduction to regulatory affairs in Middle East and Africa
- Lifecycle management – key international markets
- Maintenance of US marketing applications
- Marketing authorisation procedure in Turkey
- Regulatory requirements for marketing authorisations
- Regulatory requirements of Japan
- Updates on China regulatory reform
- US requirements for original marketing applications.

I will be enrolling on many of these webinars because they offer cost-effective training at a time that suits me. I would also recommend these webinars for "just-in-time" training – for those times when you are just about to start a new project and you need to learn the subject or refresh your knowledge.

Thinking back to time and the summer, we are halfway through the year already, have you checked whether your continuing professional development (CPD) record is up to date? As I regularly say to my teams, we are a highly regulated industry and keeping our knowledge up to date is essential. If we do not keep a record of our training and learning then, when audited, how can we prove our competence? So if you have a bit of downtime over the coming months, log onto the **TOPRA website** and update your CPD records. It might save you time as we run up to that other busy period at the end of the year.

Additionally, nominations for elections to the TOPRA Board are now open (see p3). I strongly urge you to consider standing and help shape our diverse profession.

We also have the **Brexit Roundtable on clinical development** (on 19 July, in London). After our successful Annual Summit on 3 July, where leaders and influencers gathered to share their ideas and wisdom, I hope many more of you will join us at this roundtable.

On a final note, I will be looking forward to finding out the shortlist of this year's TOPRA Awards, due out in mid-September – and of course the glamorous Awards Ceremony in November.

Institute approves apprenticeship standard

The Regulatory Affairs Specialist (Healthcare/Veterinary) apprenticeship standard has now been approved by the Institute of Apprenticeships.

The standard sets out the behaviours, skills and knowledge that apprentices must develop by the end of the 24- to 30-month apprenticeship. Having the standard in place will enable companies in the UK to use the apprenticeship levy funds to pay for the training of apprentices in all areas of regulatory affairs, including medical devices, medicines, veterinary and *in vitro* diagnostic devices. Outside the UK, the standard can be used as a benchmark against which to train and assess apprentices, and TOPRA's apprenticeship training will be available to delegates from any country.

The development of the standard, which was facilitated by TOPRA as part of its commitment to improve the pipeline of talent coming into the profession,

Robert Kneschke/Shutterstock

has been supported by a wide range of employers, including Pfizer, 3M, Amgen, AstraZeneca, Bayer, BD, Brightwake, Clinical Professionals, Galderma, Global Regulatory Services Limited, Johnson & Johnson, Norgine, NSF, Segulah Consulting, SLE, TRAC services Ltd, Vectura, and Victrex PLC.

Samantha Alsbury, TOPRA's Head of Professional Development, said: "Our next step is to gain approval for the end-point assessment plan which sets out the assessment that apprentices must complete in order to pass the apprenticeship. Employers will start recruiting apprentices soon so those interested in becoming an apprentice should keep an eye on the company websites and the TOPRA job board."

Employers who wish to find out more about how to take advantage of this opportunity should contact Samantha via email (**samantha@topra.org**). Even companies who do not pay the levy can access funds to support the training of new or current staff.

TOPRA member networks – join one now!

Sinéad Whelan, TOPRA's Head of Membership and Data Insight, explains about TOPRA's networks and online communities, and why you should join them

One of the key benefits of TOPRA membership is engaging with our popular member networks. We operate member groups through virtual communities on the **TOPRA website**.

TOPRA jargon buster

- **TOPRA Ins** A territory-based network (current groups include: Scotland, Sweden, France, Switzerland, Italy, North America, Spain, Ireland)
- **SPINS** Special interest networks (current groups include: Biotech, clinical trials, CMC, veterinary, young professionals, regulatory intelligence, eRA, MedTech, etc)
- **Steering group** A core group of volunteers who lead the various member networks
- **Communities** Online platform for members to connect with other members


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What happens in these networks

Each TOPRA In and SPIN has a steering group which lead on the activities of the group, such as coordinating free membership webinars, contributing articles to our professional journal *Regulatory Rapporteur*, coordinating TOPRA Annual Symposium sessions, and some hold regular face-to-face meetings locally. Each online community has an announcement and discussion section and also a resource library to hold useful information for members (eg, recordings of webinars).

We also have a special community set up for Brexit discussions for any member who wishes to keep up to date with ongoing developments.

Join a TOPRA network now

SPINs and TOPRA Ins are open to TOPRA members only. You can sign up to any community in the My TOPRA area on the **TOPRA website** (you need to log in first).

CALL FOR NOMINATIONS: TOPRA BOARD ELECTIONS

Join TOPRA as a Board Member and become a leader in your profession

The TOPRA Board Elections provide the opportunity for you to consider being part of the team that leads this well-respected, diverse and global professional body, making a difference to how regulatory professionals are supported in their roles

The following positions will fall vacant at the end of 2018 as the current post holders complete their terms of service

PRESIDENT-ELECT	Nominations are invited to this post, which is for a **one-year term.** The successful candidate will then serve a further one year as the TOPRA President and a final one year as Past-President. This position includes being the Chair of the Board with an important representation role.
REGIONAL DIRECTORS (2) (one with a focus on North America and one with a focus on the EU)	These are positions that are held for **two years** (for a maximum of two consecutive two-year terms). These Board Directors have oversight of the activities of TOPRA (in North America or the EU). Together with the rest of the Board they have the legal and financial responsibility for TOPRA, setting and monitoring its strategy and overseeing the work of the staff.

For more information on these roles please contact **Lynda Wight**, TOPRA Executive Director. You can also be put in touch with current Board members to hear their experience of holding office.

Why stand for election?

- ***Influence*** the work of your professional body by offering your time and talents to promoting TOPRA and the profession of regulatory affairs in general, with a chance to shape the strategy for TOPRA in these interesting times.
- ***Participate*** in the Advisory Council with leading figures in the regulatory affairs world, with opportunities to attend conferences and meetings that help develop your personal regulatory intelligence and networks.
- ***Personal development*** – raise your personal profile and, above all, have the chance to put something back into the profession.

NOMINATE NOW

To find out more information about the Board Elections including who can stand for election, what is expected of Board members and details of the Annual Review Meeting, please visit the TOPRA website.

#TOPRAelections18

HOW TO MAKE A NOMINATION

If you would like to stand for these positions you will need to complete a nomination form containing the following:

- **The signatures of three other TOPRA members**
- **A statement from you which explains why you wish to stand and what you think you would bring to the Board.**

Please note that you can only stand for **one** position on the Board.

Nominations must be received at the TOPRA Offices by email (lynda@topra.org) by close of business on Tuesday 31 July 2018.

TOPRA MEMBER ACHIEVES CHARTERED SCIENTIST STATUS

TOPRA is delighted to announce that Mojisola Ajeneye (UK Medicines and Healthcare products Regulatory Agency) has achieved recognition as a Chartered Scientist (CSci).

On achieving her CSci status, Ms Ajeneye said: "I first became aware of the chartered scientist status for regulatory specialists at the 2017 TOPRA annual symposium during one of the career workshops. The applicaton journey has allowed me to reflect on my work-based, self-learning and continuing professional development activities over the years, and how valuable they were. I would encourage fellow colleagues and those planning

to start a career in regulatory affairs to consider aiming for this prestigious status. Many thanks to my mentors and colleagues who have supported me over the years."

Chartered Scientist (CSci) accreditation

TOPRA offers Chartered Scientist (CSci) accreditation from the UK Science Council. CSci is a professional registration that recognises a high level of skill and experience independent of discipline. Apply for this international interdisciplinary accreditation today.

More information available here.

CSci
Chartered Scientist

Members-only activities

Part of TOPRA's membership benefit includes being able to network with professionals locally and to attend focused sessions virtually (eg, via webinars). Below are a selection of recent and upcoming events:

- TOPRA In Scotland meeting, 22 May
- TOPRA In Ireland meeting, 21 June
- MedTech SPIN webinar, 29 June
- TOPRA In Sweden meeting, 5 September

More information about **TOPRA In groups** and **webinars** available on the TOPRA website.

Be prepared for a "hard" Brexit, delegates at TOPRA Roundtable told

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Details of the proposed transition agreement for Brexit remain unclear

Regulatory affairs professionals and stakeholders met on 14 June 2018 at TOPRA's headquarters in London, UK, to discuss challenges facing the profession as Brexit approaches.

Although there are fewer than 10 months before the UK officially leaves the EU on 29 March 2019, details of the proposed transition agreement remain unclear, and it is expected that negotiations will be ongoing right down to the wire.

Concerns have been expressed that the terms for the UK withdrawal agreement, which are subject to ongoing negotiations until later this year, will not be as accommodating as hoped. Delegates at the meeting discussed the consequences of Brexit for regulatory processes, which are far-reaching.

A summary of the discussions is available on the **TOPRA website**. The next **Brexit Roundtable on clinical development** will be held on 19 July.

Consultations: Share your views

TOPRA aims to keep members informed of agency and government consultations that are relevant to regulatory affairs as they are issued.

We realise that many members are able to make comments on public consultations through their employing organisations or the trade associations. However, these avenues are not available to everyone and individual regulatory practitioners might have additional observations to make from a personal or professional perspective.

To view the latest consultations, visit our Consultations page to make your voice heard. You can also email us your views.

TOPRA welcomes new member to Advisory Council

TOPRA is delighted to welcome Daniela Drago as a new member of its Advisory Council. Dr Drago is Director of Regulatory Affairs at the School of Medicine and Health Sciences, The George Washington University, Washington DC, US. She has worked with TOPRA on developing its competency framework and has been a member of the professionalism committee.

NEW FELLOWS OF TOPRA

Mel Munro (left) and Paul Browning have been made Fellows of TOPRA. Dr Munro has over 16 years' experience in the development and registration of veterinary medicinal products. She has been responsible for the execution of over 400 regulatory products for more than 110 different animal health companies. Mr Browning has been running regulatory affairs departments since 2006. He has previously worked at the UK Ministry of Defence, where he obtained regulatory and quality approvals for *in vitro* diagnostic medical devices.

NEWTOPRAMEMBERS

TOPRA welcomes the following new and returning members

Anne Blake, Regulatory Affairs Associate, Pfizer Australia

Ms Tonia Baggio, student, Ireland

Ms Yvonne Janet Bassett, Associate Director, Merck Serono SA Geneva, Switzerland

Miss Kolsue Begum, Regulatory affairs officer, Thorton & Ross Ltd, UK

Mrs Ildiko Campbell*, Regulatory Affairs Specialist, Armstrong Medical Ltd, UK

Mrs Robo Caroline*, Director, Regulatory Affairs Drugs and Biologics, Blue Reg, France

Dr James Desiderio, Vice-President, Regulatory Affairs, Acceleron Pharma, Massachusetts, US

Ms Jeannette Marrero Coto, Regulatory Affairs Executive, Orphix Consulting GmbH, Germany

Mrs Janet Fitzgerald*, Regulatory Affairs Manager Biosimilars, Hospira UK Ltd, UK

Mr Lakshmeenaravana Goundalkar*, Vice-President, Celegence LLC, Illinois, US

Mrs Martine C Hallows, Regulatory Manager, Teva, UK

Dr Rajiv Harimoorthy, Researcher, University of Gothenburg, Sweden

Ms Salma Husain, Senior Medical Device Specialist, Medicines and Healthcare products Regulatory Agency, UK

Mr Jonnathon Killick*, Regulatory Affairs Assistant, Gilead Sciences International Ltd, UK

Miss Maria Kosma, student, UK

Mr Paul Malinovski*, Manager EMEA, Medical Writing and Regulatory Services, NAMSA, Germany

Dr Yannick Martinez, Assistant, Unviersity of Lausanne, France

Dr Clare McAleer*, Director, Pfizer Australia

Mrs Jennifer Millband, Senior Manager, Regulatory Affairs, Pfizer Ltd, UK

Mr Joel Alexander Mitchell*, Regulatory Affairs Associate, Rest of World Commercial, Gilead Sciences International Ltd, UK

Mr Mahmood Mitchla, Regulatory Affairs Specialist, AstraZeneca UK Ltd, UK

Ruby Osman, medical device regulatory affairs student, Ireland

Dr Franz-Josef Rehmann, Regulatory CMC Associate Director – Small Molecules, AstraZeneca R&D Mölndal, Sweden

Mr Glen Rockwell, Associate Director, Regulatory CMC, AstraZeneca R&D Mölndal, Sweden

Dr Celina Seeto*, Senior Regulatory Affairs Associate, Boehringer Ingelheim, Australia

Dr Babu Selvam, Regulatory Labelling Strategy Lead, Shire Pharmaceuticals – Cambridge, Massachusetts, US

Mrs Nathalie Thvssen, Manager, 4 Global Lean RA, Belgium

Ms Helen Vella, Director, Licensing, Malta Medicines Agency, Malta

Dr Federica Vinciati, Regulatory Affairs Manager – Europe, UBC, UK

**Registered Member (MTOPRA)*

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